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APPLICATION NO. **FILING DATE FIRST NAMED INVENTOR** ATTORNEY DOCKET NO.

09/550,173

04/14/00

OOE

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2185-0424-SP

HM22/0103 |

BIRCH STEWART KOLASCH & BIRCH LLP P 0 BOX 747

FALLS CHURCH VA 22040-0747

EXAMINER DAVIS, K ART UNIT PAPER NUMBER

1636

DATE MAILED:

01/03/01

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

	Ammiliantia - Na	<u>. </u>					
	Application No.	Applicant(s)					
Offic Action Summary	09/550,173	OOE ET AL.					
,	Examiner	Art Unit					
	Katharine F. Davis	1636					
The MAILING DATE of this communication appe Period for Reply	ars on the cover sheet wit	th the correspondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	16 (a). In no event, however, may a within the statutory minimum of thir ill apply and will expire SIX (6) MON cause the application to become A	reply be timely filed ty (30) days will be considered timely. THS from the mailing date of this communication.					
1) Responsive to communication(s) filed on April	14,2000 and August 14	and 28, 2000 .					
	s action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-16</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdraw	n from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-16</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claims are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examine	r.	·					
10) The drawing(s) filed on is/are objected to	by the Examiner.						
11) The proposed drawing correction filed on	is: a) approved b) □	disapproved.					
12) The oath or declaration is objected to by the Ex							
Priority under 35 U.S.C. § 119							
13)⊠ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. &	i 119(a)-(d).					
a)⊠ All b)□ Some * c)□ None of:							
1. Certified copies of the priority documents	have been received.						
2. Certified copies of the priority documents		oplication No.					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of							
14) Acknowledgement is made of a claim for domes	uc pnority under 35 U.S.(∪. & 119(e).					
		•					
Attachment(s)							
15) Notice of References Cited (PTO-892) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3	19) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152) htice To Comply . J					

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DETAILED ACTION

This Office Action is in response to the application filed on April 14, 2000 and to the Information Disclosure Statements filed on August 14 and August 28, 2000. Claims 1-16 are pending in the instant application.

Specification

The abstract of the disclosure is objected to because it contains more than the one required paragraph. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informality: the use of the term "allylhydrocarbon receptor". The "allylhydrocarbon receptor" is not a known term in the art for a receptor of dioxin. For examination purposes the correct term is assumed to be "aryl hydrocarbon receptor". Appropriate correction is required.

The specification contains nucleotide and/or amino acid sequences (on pages 19, 43, 44, 46, 47, 50, 51, 64, 65, 69, 70, 72, 73, 79 and 81-85) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the

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reason set forth on the attached Notice To Comply With Requirements For Patent Applications
Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. Applicant must
provide a paper copy and a computer readable copy of the Sequence Listing and a statement that
the content of the paper and computer readable copies are the same and, where applicable,
include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or
1.825(d). A full response to this Office action must include a complete response to the
requirement for a new Sequence Listing.

Claim Objections

Claim 14 is objected to because of the following informality: the recitation of the phrase "naturally having". This phrase is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex

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parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F.

Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 provides for the use of an animal cell for evaluating an agonist activity or an antagonist activity of a chemical substance over the transcription promoting ability of a ligand-responsive transcription control factor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 2, 9 and 14 are indefinite in the recitation of the phrase "substantially consists of". The definition of the phrase on pages 20-21 of the instant specification is not sufficient to clearly define the metes and bounds of the claims.

Claims 3, 4 and 9-13 are indefinite in the recitation of the term "allylhydrocarbon receptor." The "allylhydrocarbon receptor" is not a known term in the art for a receptor of dioxin. For examination purposes the correct term is assumed to be "aryl hydrocarbon receptor".

Claim 9 recites the limitation "said responsive transcription control factor" in lines 11-12. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans *et al.* (US Patent 5,298,429: IDS reference). Evans *et al.* teaches a mammalian cell containing non-endogenous DNA which expresses a hormone receptor (said receptor can be an intranuclear hormone receptor, estrogen receptor, androgen receptor and/or a thyroid hormone receptor) and a DNA sequence which expresses a hormone response element operatively linked to a reporter gene sequence. The test cell of Evans *et al.* is made by introducing into said cell

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plasmids which contain the non-endogenous DNA sequences and selection marker gene sequences for propagation of the plasmids in the test cells. The non-endogenous DNA sequences are eukaryotic sequences which are known in the art to have TATA box promoter sequences. The test cells are employed in a method for determining whether a substance is a hormone receptor agonist or a hormone receptor antagonist. The test cells are cultured in the presence of the substance and the expression of the reporter gene is monitored to assess transcription activity. The test cells with reagents for making and using the test cells can be contained in a kit. The elements in claims 1, 2, 5-8 and 10-15 read on the test cells and bioassay of Evans *et al.* (see entire document).

Claims 1-5 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bradfield *et al.* (US Patent 5,650,283: IDS reference). The test cells and methods of Bradfield *et al.* are akin to those of Evans *et al.* with the exception that Bradfield *et al.* teaches a test cell which is modified to express the intranuclear dioxin receptor (Ah receptor or aryl hydrocarbon receptor) and its dimerization partner, the Arnt receptor. The elements in claims 1-5 and 9-15 read on the test cells and bioassay of Bradfield *et al.* (see entire document).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans *et al.* (US Patent 5,298,429: IDS reference). Claim 16 requires that the plasmid encoding the receptor gene have a different selectable marker from the plasmid encoding the reporter gene. Evans *et al.* teaches cotransfection of both plasmids into the test cells however does not specifically teach that the cotransfected plasmids have different selection markers. It is well known in the art that when carrying out a cotransfection protocol it is advantageous to use different selection markers for each plasmid in order to be sure that each plasmid was successfully taken up by the cell. One of skill in the art would be motivated to use different selection markers as a control method in cotransfection protocols. Therefore it would have been obvious to a person of ordinary skill in

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the art at the time that the instant invention was made to use different selection marker genes for

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each plasmid when carrying out cotransfection protocols.

Conclusion

Claims 1-16 are rejected. Any inquiry concerning this communication or earlier

communications from the examiner should be directed to Katharine F. Davis whose telephone

number is (703) 605-1195. The examiner can normally be reached on Monday-Friday (8:30am-

5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Richard Schwartz can be reached on (703) 308-1133. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 308-4242 for regular

communications and (703) 305-1935 for After Final communications. Any inquiry concerning

the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose

telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of

this application or proceeding should be directed to the receptionist whose telephone number is

(703) 308-0196.

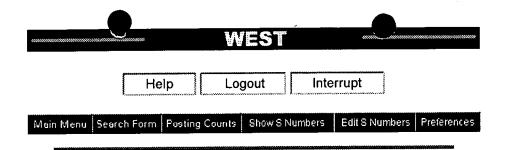
Katharine F. Davis/KFD

January 2, 2001

ROBERT A. SCHWARTZMAN

PRIMARY EXAMINER

DB Name	Query	Hit Count		
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USPT,JPAB,EPAB,DWPI,TDBD	evans-ronald-m.in.	110	<u>L11</u>	to paper #6
USPT,JPAB,EPAB,DWPI,TDBD	evans-ronald.in.	5	<u>L10</u>	10 paper
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Search Results -

Term	Documents
HORMONE.DWPI,TDBD,EPAB,JPAB,USPT.	34536
HORMONES.DWPI,TDBD,EPAB,JPAB,USPT.	26068
RECEPTO\$	0
RECEPTO.DWPI,TDBD,EPAB,JPAB,USPT.	51
RECEPTOC.DWPI,TDBD,EPAB,JPAB,USPT.	1
RECEPTOCLE.DWPI,TDBD,EPAB,JPAB,USPT.	1
RECEPTOD.DWPI,TDBD,EPAB,JPAB,USPT.	1
RECEPTODE.DWPI,TDBD,EPAB,JPAB,USPT.	1
RECEPTOE.DWPI,TDBD,EPAB,JPAB,USPT.	1
RECEPTOE-BINDING.DWPI,TDBD,EPAB,JPAB,USPT.	1
(L11 AND HORMONE RECEPTO\$).USPT,JPAB,EPAB,DWPI,TDBD.	61

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Search History

Today's Date: 12/29/2000

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DIALOG INFORMATION SERVICES
PLEASE LOGON:
 ****** HHHHHHHH SSSSSSS?
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ENTER PASSWORD:
 ****** HHHHHHHH SSSSSSS? ******
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Author(s): DARDEL F; HIREL PH; MECHULAM Y; MELLOT P
Corporate Source: ECOLE POLYTECH, BIOCHIM LAB, CNRS/F-91128
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Journal: BIOFUTUR, 1987, N62, P83-86
Language: FRENCH Document Type: ARTICLE
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 (c) 1998 Inst for Sci Info. All rts. reserv.
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Author(s): GRIFFITHS K; DAVIES P; EATON CL; HARPER ME; PEELING WB; TURKES
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 Journal: OXFORD REVIEWS OF REPRODUCTIVE BIOLOGY, 1987, V9, P192-259
Language: ENGLISH Document Type: REVIEW, BIBLIOGRAPHY
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7/3/3 DIALOG(R)File 434:SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. 08697518 Genuine Article#: M8229 No. References: 40 Title: STEROID BINDING AT SIGMA-RECEPTORS SUGGESTS A LINK BETWEEN ENDOCRINE, NERVOUS, AND IMMUNE-SYSTEMS Author(s): SU TP; LONDON ED; JAFFE JH Corporate Source: NIDA, ADDICT RES CTR, POB 5180/BALTIMORE//MD/21224 Journal: SCIENCE, 1988, V240, N4849, P219-221 Language: ENGLISH Document Type: ARTICLE 7/3/4 DIALOG(R) File 434: SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. Genuine Article#: M3026 No. References: 55 08636885 Title: EVALUATION OF ESTRADIOL BINDING IN HUMAN BENIGN PROSTATIC HYPERPLASTA Author(s): GANESAN S; BASHIRELAHI N; YOUNG JD Corporate Source: UNIV MARYLAND, SCH DENT, DEPT BIOCHEM/BALTIMORE//MD/21201; UNIV MARYLAND, SCH MED, DEPT SURG, DIV UROL/BALTIMORE//MD/21201 Journal: JOURNAL OF CLINICAL LABORATORY ANALYSIS, 1988, V2, N1, P25-34 Language: ENGLISH Document Type: ARTICLE 7/3/5 DIALOG(R) File 434: SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. Genuine Article#: M1851 No. References: 217 08623514 Title: STEROID EFFECTS ON EXCITABLE-MEMBRANES Author(s): ERULKAR SD; WETZEL DM Corporate Source: UNIV PENN, SCH MED, DEPT PHARMACOL/PHILADELPHIA//PA/19104 Journal: CURRENT TOPICS IN MEMBRANES AND TRANSPORT, 1987, V31, P141-190 Language: ENGLISH Document Type: ARTICLE DIALOG(R) File 434: SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. 08503625 Genuine Article#: L3343 No. References: 41 Title: PITUITARY-TESTICULAR FUNCTION OF PROSTATIC-CANCER PATIENTS DURING TREATMENT WITH A GONADOTROPIN-RELEASING HORMONE *AGONIST* ANALOG .2. ENDOCRINOLOGY AND HISTOLOGY OF THE TESTIS Author(s): HUHTANIEMI I; NIKULA H; PARVINEN M; RANNIKKO S Corporate Source: UNIV TURKU, DEPT PHYSIOL, KIINAMYLLYNKATU 10/SF-20520 TURKU 52//FINLAND/; UNIV TURKU, DEPT ANAT/SF-20520 TURKU 52//FINLAND/; UNIV HELSINKI, DEPT CLIN CHEM/SF-00100 HELSINKI 10//FINLAND/; UNIV HELSINKI, DEPT SURG 2/SF-00100 HELSINKI 10//FINLAND/ Journal: JOURNAL OF ANDROLOGY, 1987, V8, N6, P363-373 Language: ENGLISH Document Type: ARTICLE DIALOG(R)File 434:SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. 08055196 Genuine Article#: H0329 No. References: 154 Title: HORMONE AGONISTS AND ANTAGONISTS IN THE TREATMENT OF HORMONE SENSITIVE BREAST AND PROSTATE-CANCER Author(s): NICHOLSON RI; WALKER KJ; DAVIES P Corporate Source: UNIV WALES COLL MED, TENOVUS INST CANC RES, HEATHPK/CARDIFF CF4 4XX/S GLAM/WALES/ Journal: CANCER SURVEYS, 1986, V5, N3, P463-486 Language: ENGLISH Document Type: REVIEW, BIBLIOGRAPHY

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GENE-EXPRESSION IN THE PROSTATE - AN HYPOTHESIS
Author(s): TENNISWOOD M
Corporate Source: UNIV OTTAWA, DEPT BIOCHEM/OTTAWA K1H 8M5/ONTARIO/ĊANADA/
Journal: PROSTATE, 1986, V9, N4, P375-385

07698463 Genuine Article#: F1954 No. References: 58

Title: ROLE OF EPITHELIAL-STROMAL INTERACTIONS IN THE CONTROL OF

Language: ENGLISH Document Type: ARTICLE 7/3/13 DIALOG(R) File 434: SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. 07607035 Genuine Article#: E6130 No. References: 682 Title: THE ELECTRICAL DIMENSION OF CELLS - THE CELL AS A MINIATURE ELECTROPHORESIS CHAMBER Author(s): DELOOF A Corporate Source: CATHOLIC UNIV LEUVEN, INST ZOOL/B-3000 LOUVAIN//BELGIUM/ Journal: INTERNATIONAL REVIEW OF CYTOLOGY, 1986, V104, P251-352 Language: ENGLISH Document Type: REVIEW, BIBLIOGRAPHY 7/3/14 DIALOG(R)File 434:SciSearch(R) Cited Ref Sci (c) 1998 Inst for Sci Info. All rts. reserv. Genuine Article#: A6254 No. References: 37. Title: PROSTATE-CANCER - BIOLOGICAL BASIS FOR THE INCLUSION OF AN ANTIANDROGEN IN THE TREATMENT Author(s): RAYNAUD JP; COUSSEDIERE D; MOGUILEWSKY M; POTTIER J; LABRIE F Corporate Source: ROUSSEL UCLAF/F-75007 PARIS//FRANCE/; CHU LAVAL/QUEBEC CITY G1V 4G2/QUEBEC/CANADA/ Journal: BULLETIN DU CANCER, 1986, V73, N1, P36-46 Language: FRENCH Document Type: ARTICLE ?s tata box S8 O TATA BOX ?ds Items Description ALLYLHYDROCARBON RECEPTO? S1 0 S2 0 ALYLHYDROCARBON RECEPTO? s3 ARNT 1 HORMONE RECEPTOR? S4 1847 **S**5 52 S4 AND AGONIST 56 14 S5 AND ESTROGEN 14 RD (unique items) TATA BOX S8 ?logoff 29dec00 15:38:05 User259980 Session D61.3 \$11.98 0.918 DialUnits File434 \$52.50 14 Type(s) in Format 3 \$3.75 1 Type(s) in Format 9 \$56.25 15 Types \$68.23 Estimated cost File434 \$0.35 TYMNET \$68.58 Estimated cost this search \$69.29 Estimated total session cost 1.094 DialUnits

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